IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Alvogen Pine Brook LLC, Plaintiff, v. Noven Pharmaceuticals, Inc. and Hisamitsu Pharmaceutical Co., Inc., Defendants.	C. A. No. _____

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Alvogen Pine Brook LLC ("Alvogen"), through counsel, hereby brings this Complaint for Declaratory Judgment against Noven Pharmaceuticals, Inc. ("Noven") and Hisamitsu Pharmaceutical Co., Inc. ("Hisamitsu") (collectively, "Defendants"), and allege as follows:

INTRODUCTION

1. This is a declaratory judgment action seeking a declaration of noninfringement of U.S. Patent Nos. 6,841,716 ("the '716 patent") and 8,231,906 ("the '906 patent") to enable Alvogen to bring its generic estradiol transdermal film products of 0.025 mg/24 hours, 0.0375 mg/24 hours, 0.05 mg/24 hours, 0.075 mg/24 hours and 0.1 mg/24 hours to market at the earliest possible date under the applicable statutory and regulatory provisions and to allow the public to enjoy the benefits of generic competition for these products.

THE PARTIES

2. Alvogen Pine Brook LLC is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 10 Bloomfield Avenue, Pine Brook, New Jersey 07058.

3. On information and belief, Noven is a Delaware corporation with a principal place of business at 11960 S.W. 114th Street, Miami, Florida 33186.

4. On information and belief, Hisamitsu is a Japanese corporation with a principal place of business at Saga, Tosu, Tashirodiakan-machi, 408, Japan 841-0017.

5. On information and belief, Noven is a wholly-owned subsidiary of Hisamitsu.

6. On information and belief, the acts of Noven complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Hisamitsu.

JURISDICTION AND VENUE

7. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984 (codified as amended at 21 U.S.C. § 355) (the "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 17 Stat. 2066 (2003) (the "MMA"), based upon an actual controversy between the parties to declare that Alvogen is free, upon approval by the Food and Drug Administration's ("FDA"), to manufacture, use, market, sell, offer to sell and/or import its Estradiol Film, Extended Release product as described in Alvogen's abbreviated new drug application ("ANDA") No. 208548 ("Alvogen's ANDA Product").

8. This Court has original jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Defendants by virtue of their specific acts in, and their systematic and continuous contacts with, the State of Delaware, including

conducting substantial and regular business therein through marketing and sales of pharmaceutical products in Delaware, including but not limited to products containing estradiol in dosage strengths 0.025 mg/24 hours, 0.0375 mg/24 hours, hours, 0.05 mg/24 hours 0.075 mg/24 and 0.1 mg/24 hours. Personal jurisdiction over Noven in this Court is further appropriate because Noven is a Delaware corporation.

10. On information and belief, Defendants regularly conduct or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware, including through their own actions and/or the actions of their affiliates and agents, demonstrating that Defendants have continuous and systematic contacts with Delaware.

11. On information and belief, Defendants have previously availed themselves of this forum and affirmatively involved this Court's jurisdiction by litigating as plaintiffs, including, for example, Noven Pharmaceuticals, Inc. v. Actavis Laboratories UT, Inc., No. 1:15-cv-00249-LPS and Noven Pharmaceuticals, Inc. and Hisamitsu Pharmaceutical Co., Inc. v. Mylan Technologies Inc., Mylan Pharmaceuticals Inc., and Mylan Inc., No. 1:15-cv-00328-LPS.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

PATENTS IN SUIT

13. On its face the '716 patent, entitled "Patch," indicates that it was issued by the United States Patent and Trademark Office on January 11, 2005. A copy of the '716 patent is attached as Exhibit A.

14. According to the records at the United States Patent and Trademark Office, Hisamitsu is the assignee of the '716 patent.

15. On its face the '906 patent, entitled "Transdermal Estrogen Device and Delivery," indicates it was issued by the United States Patent and Trademark Office on July 13, 2012. A copy of the '906 patent is attached as Exhibit B.

16. According to the records at the United States Patent and Trademark Office, Noven is the assignee of the '906 patent.

BACKGROUND

New Drugs and Patent Listing Requirements

17. Before marketing a new drug in the United States, a manufacturer must submit a New Drug Application ("NDA") to FDA, and FDA must approve it. Once approved, new drugs generally are referred to as brand name drugs because they are marketed under a trade name or trademark for the drug product rather than the chemical name for the active ingredient in the drug product.

18. In addition to the technical data submitted in an NDA, a brand name drug manufacturer is required to submit to FDA information on each patent that claims the drug or a method of using the drug that is the subject of the NDA with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, sale or importation of the drug product. A brand name drug manufacturer should submit patent information – the patent's number and its expiration date – in connection with its NDA if the patent claims a drug or claims a method of using the drug covered by the NDA. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53.

19. Once FDA approves an NDA, FDA lists the patent information submitted by the brand name drug manufacturer in its publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). 21 U.S.C. § 355(b)(1).

Generic Drug Applications and Patent Certification Requirements

20. A generic drug is a version of a brand name drug that is generally sold without a trade name or trademark for the drug product.

21. Before marketing a generic drug in the United States, a manufacturer must submit an ANDA to FDA, and FDA must approve it. An ANDA applicant must show that its generic drug is bioequivalent to the previously approved brand name drug.

22. Generic drugs typically enjoy a significant price advantage over their brand name counterparts. Consequently, generic drugs are frequently prescribed in an effort to control healthcare costs. Generic drugs represent a substantial and increasing portion of the medicines used in the United States.

23. A generic drug manufacturer seeking FDA approval for a generic version of a brand name drug product must file one of four certifications with FDA: (i) that the brand name drug manufacturer has not filed patent information with FDA; or, for each patent listed in the Orange Book as claiming the brand name drug or a method of use for which the ANDA applicant is seeking approval; (ii) that the patent has expired; (iii) that the patent expires on a date before which the generic manufacturer is seeking to market its generic product; or (iv) that the patent claiming the brand name drug is invalid, unenforceable, or will not be infringed by the manufacturer, use or sale of the generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12)(i)(a)(4). The final certification is commonly referred to as a Paragraph IV certification.

24. If an ANDA applicant submits an ANDA with a Paragraph IV certification to FDA, it is required to notify the patent owner and the holder of the approved NDA. The filing of an ANDA with a Paragraph IV certification creates jurisdiction so that a brand name drug

manufacturer may commence an action for patent infringement against the ANDA applicant. See 35 U.S.C. § 271(e)(2).

Generic Marketing Exclusivity

25. In order to encourage generic market entry, the first ANDA applicant to file a "substantially complete" ANDA with a Paragraph IV certification (the "First Filer") is given a 180-day period in which it is the only applicant allowed to market a generic version of the brand name product. This is commonly referred to as the 180-day exclusivity period.

26. In December 2003, Congress passed the MMA. Title XI of that Act is entitled "Access to Affordable Pharmaceuticals" and includes a provision allowing an ANDA applicant to bring a declaratory judgment action for invalidity or non-infringement of an Orange Book listed patent if the NDA holder does not sue within 45 days of receiving notice of a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(C).

27. In order to prevent a First Filer from unduly delaying generic market competition, the MMA also added provisions whereby the First Filer forfeits the 180-day exclusivity period. 21 U.S.C. § 355 (j)(5)(D). One such forfeiture provision provides that the First Filer forfeits the 180-day exclusivity period if it does not market its product within 75 days after "a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent [which entitled the first applicant to exclusivity] is invalid or not infringed." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

Noven's NDA and Patent Certifications by ANDA Filers

28. On information and belief, Noven is the current holder of approved NDA No. 203752 for Minivelle® Transdermal Film, Extended Release containing estradiol in dosage

strengths 0.025 mg/24 hours, 0.0375 mg/24 hours, 0.05 mg/24 hours 0.075 mg/24 and 0.1 mg/24 hours.

29. Noven identified the '716 and '906 patents to FDA for listing in the Orange Book as patents to which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

30. As a consequence of listing the '716 and '906 patents in the Orange Book, Noven maintains, and has affirmatively represented to FDA and the public, that the '716 and '906 patents claim the drug approved in NDA 203752, and that a claim of patent infringement could reasonably be asserted against any unlicensed ANDA applicant, including Alvogen, seeking FDA approval to market a generic version of the drug prior to the expiration of the '716 and '906 patents.

31. Alvogen submitted a Paragraph IV certification in ANDA 208548, certifying that the '716 and '906 patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, and/or sale of Alvogen's ANDA Product.

32. On October 27, 2015, Alvogen sent a Notice Letter to Defendants notifying them that Alvogen filed ANDA No. 208548 with FDA with a Paragraph IV certification to the '716 and '906 patents. Defendants received the Notice Letter on October 28, 2015. The Notice Letter included a detailed statement of the factual and legal bases for Alvogen's Paragraph IV certification and an Offer of Confidential Access to Alvogen's ANDA No. 208548 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

33. Alvogen's submission of ANDA No. 208548 to FDA containing a Paragraph IV certification to the '716 and '906 patents creates the necessary case or controversy and subject

matter jurisdiction for Alvogen to obtain declaratory judgment against Defendants regarding infringement of the '716 and '906 patents.

34. As of December 14, 2016, the next Monday occurring 45 days after Defendants received the Notice Letter, Defendants did not bring an action for infringement of the '716 and '906 patents against Alvogen. As of today's date, Defendants have still not brought an action for infringement of the '716 and '906 patents against Alvogen.

35. Pursuant to 21 U.S.C. § 355(j)(5)(C), an ANDA applicant may bring a declaratory judgment action for invalidity or noninfringement of an Orange Book listed patent if neither the NDA holder nor patent owner files suit within 45 days of receiving the notice letter, provided that an offer of confidential access accompanied the notice letter in an instance where the notice letter asserts noninfringement.

36. Defendants did not file suit against Alvogen within 45 days of receiving Alvogen's Notice Letter.

37. Alvogen remains under threat of an infringement suit relating to the '716 and '906 patents because the 45-day window under 21 U.S.C. § 355(j)(5)(B)(iii) does not preclude Defendants from pursuing subsequent patent infringement suits relating to ANDA No. 208548 against Alvogen under 35 U.S.C. § 271(e)(2)(A) or, upon FDA approval of ANDA No. 208548, under 35 U.S.C. §§ 271(a), (b) and/or (c).

38. On information and belief, Defendants have asserted the '716 and '906 patents against Mylan Technologies Inc., Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively "Mylan").

39. On information and belief, regarding Noven's NDA 203752, Mylan is the first entity to file an ANDA with a Paragraph IV certification to the '716 and '906 patents, rendering Mylan eligible to receive the 180-day exclusivity period.

40. On information and belief, FDA will not approve Alvogen's ANDA No. 208548 until Mylan's 180-day exclusivity period is either forfeited or runs out.

41. Among other things, a final and nonappealable judgment of noninfringement or invalidity of the '716 and '906 patents would trigger the forfeiture of Mylan's 180-day exclusivity period, allowing Alvogen to obtain FDA approval to market its ANDA Product. Absent such judgment, FDA approval of Alvogen's ANDA may be indefinitely delayed.

42. Actual and justiciable controversies exist between Alvogen and Defendants relating to the '716 and '906 patents.

COUNT 1: DECLARATION OF NONINFRINGEMENT OF THE '716 PATENT

43. Alvogen repeats and realleges Paragraphs 1-42 as if fully set forth herein.

44. An actual and justiciable controversy exists between Alvogen and Defendants regarding the noninfringement of the '716 patent.

45. The '716 patent issued with eight claims, of which only claim 1 is independent.

46. Independent claim 1 of the '716 patent recites a patch provided with a support, an adhesive layer laminated on one side of the support, and a release film attached in a releasable manner to said adhesive layer and having a slit running from one edge to the opposite edge, wherein the patch is characterized in that, *inter alia*, a "wave-shaped slit of said release film is 6 mm to 12.5 mm, and the wave height of each said wave-shaped slit of said release film is 4 mm to 8 mm."

47. Alvogen's ANDA Product does not meet each and every limitation of claim 1 at least because Alvogen's ANDA Product does not contain a patch with a release film having a slit

wherein the shape of the slit in the release film is a wave shape such that the wave pitch of the wave-shaped slit of the release film is 6 mm to 12.5 mm and the wave height of the wave-shaped slit of the release film is 4 mm to 8 mm as required by claim 1 of the '716 patent.

48. Because Alvogen's ANDA Product does not meet each and every limitation of independent claim 1, Alvogen's ANDA Product does not meet each and every limitation of dependent claims 2-8.

49. Because Alvogen's ANDA Product does not meet each and every limitation of any claim of the '716 patent, the submission of ANDA No. 208548 by Alvogen does not constitute infringement of any claim of the '716 patent.

50. Alvogen is entitled to a declaration that the submission of ANDA No. 208548 by Alvogen does not infringe the '716 patent.

51. Because Alvogen's ANDA Product does not meet each and every requirement of any claim of the '716 patent, the commercial manufacture, use, sale, offer for sale or importation of Alvogen's ANDA Product does not and will not constitute infringement of any claim of the '716 patent.

52. Alvogen is entitled to a declaration that the commercial manufacture, use, sale, offer for sale or importation of Alvogen's ANDA Product does not and will not infringe the '716 patent.

COUNT 2: DECLARATION OF NONINFRINGEMENT OF THE '906 PATENT

53. Alvogen repeats and realleges Paragraphs 1-52 as if fully set forth herein.

54. An actual and justiciable controversy exists between Alvogen and Defendants regarding the noninfringement of the '906 patent.

55. The '906 patent issued with fourteen claims, of which claims 1, 10, 11 and 13 are independent.

56. Independent claims 1 and 10 of the '906 patent recite a monolithic transdermal drug delivery system for estradiol, comprising a single polymer matrix layer wherein the polymer matrix layer has, *inter alia*, "a coat weight selected from the group consisting of 12.5 mg/cm^2 and 15 mg/cm^2." Independent claims 11 and 13 of the '906 patent recite a method for administering estradiol to a subject in need thereof of a monolithic transdermal drug delivery system and a method of making a monolithic transdermal drug delivery system for administering estradiol, respectively, comprising a polymer matrix with, *inter alia*, "a coat weight selected from the group consisting of 12.5 mg/cm^2 and 15 mg/cm^2."

57. Alvogen's ANDA Product does not meet each and every limitation of claims 1, 10, 11 and 13 at least because Alvogen's ANDA Product does not contain a polymer matrix with a coat weight selected from the group consisting of 12.5 mg/cm^2 and 15 mg/cm^2.

58. Because Alvogen's ANDA Product does not meet each and every limitation of independent claims 1, 10, 11 and 13, Alvogen's ANDA Product does not meet each and every limitation of dependent claims 2-9, 12 and 14.

59. Because Alvogen's ANDA Product does not meet each and every limitation of any claim of the '906 patent, the submission of ANDA No. 208548 by Alvogen does not constitute infringement of any claim of the '906 patent.

60. Alvogen is entitled to a declaration that the submission of ANDA No. 208548 by Alvogen does not infringe the '906 patent.

61. Because Alvogen's ANDA Product does not meet each and every requirement of any claim of the '906 patent, the commercial manufacture, use, sale, offer for sale or importation of Alvogen's ANDA Product does not and will not constitute infringement of any claim of the '906 patent.

62. Alvogen is entitled to a declaration that the commercial manufacture, use, sale, offer for sale or importation of Alvogen's ANDA Product does not and will not infringe the '906 patent.

PRAYER FOR RELIEF

WHEREFORE, Alvogen respectfully requests that the Court enter judgment as follows:

A. that Alvogen does not infringe the '716 and '906 patents;

B. that the submission of ANDA No. 208548 by Alvogen does not constitute infringement of the '716 or '906 patents;

C. that the commercial manufacture, use, sale, offer for sale or importation of Alvogen's ANDA Product does not and will not infringe the '716 and '906 patents;

D. that Defendants, their officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with Defendants be preliminarily and permanently enjoined from using the '716 and '906 patents to block, hamper, hinder or obstruct FDA approval and/or the commercial manufacture, use, sale, offer for sale or importation of the products described in ANDA No. 208548; and

E. that Alvogen be awarded such other and further relief as the Court deems just and proper.

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